

(19)



Europäisches Patentamt

European Patent Office

Office européen des brevets



(11)

EP 1 329 238 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
23.07.2003 Bulletin 2003/30

(51) Int Cl.7: A61M 16/00

(21) Application number: 02025428.0

(22) Date of filing: 15.11.2002

(84) Designated Contracting States:
AT BE BG CH CY CZ DE DK EE ES FI FR GB GR
IE IT LI LU MC NL PT SE SK TR
Designated Extension States:
AL LT LV MK RO SI

(71) Applicant: Siemens-Elema AB
171 95 Solna 1 (SE)

(72) Inventors:
• Ahlmén, Christer
192 51 Sollentuna (SE)
• Hallbäck, Magnus
167 38 Bromma (SE)

(30) Priority: 17.01.2002 SE 0200114

(54) Device for ventilatory system

(57) A device (2) for ventilator systems (4), said device (2) being intended for reducing dead space (12) in the ventilator system (4) and comprises a first tube (24), connectable to the dead space (12) in the ventilator system (4) for supplying a path of flow for the transport of gas from dead space (12) in the ventilator system (4), a suction means (18, 22), connected to the first tube (24), for generating an adjustable negative pressure in the first tube (24), a second tube (26), connectable to dead space (12) in the ventilator system (4), for supplying a path of flow for the transport of gas to dead space (12) in the ventilator system (4), a pumping means (20, 22),

connected to the second tube (26), for generating an adjustable positive pressure in the second tube (26) and a control unit (30) devised to regulate the suction means (18, 22) and the pumping means (20, 22) are disclosed. The device (2) is devised so the suction means (18, 22) and the pumping means (20, 22) consist of a first chamber (18) and a second chamber (20) respectively in an enclosure (16), separated by a gas-tight, moving partition (22), the control unit (30) being devised to regulate the moving partition (22) in regulating the suction means (18, 22) and the pump means (20, 22), for the purpose of achieving simpler and more reliable operation.

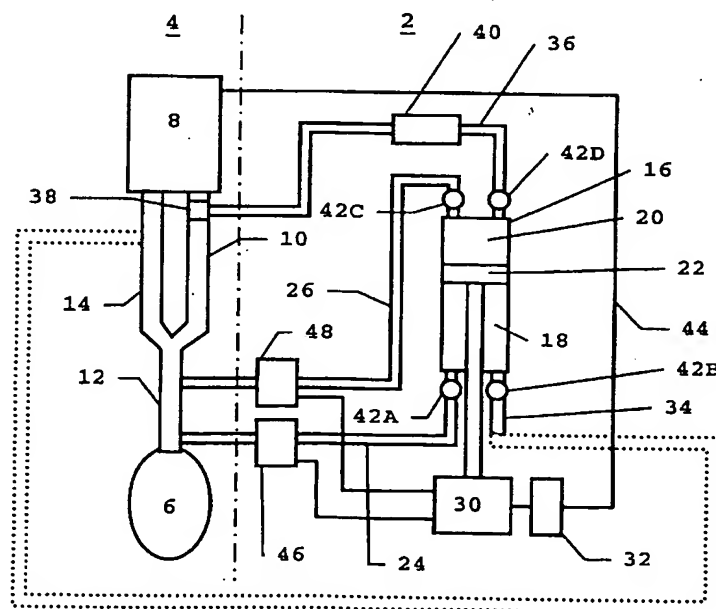


FIG. 1

EP 1 329 238 A1

Description

[0001] The present invention relates to a device for a ventilator system according to the preamble to claim 1.

[0002] In the mechanical ventilation of a patient with a ventilator system (in intensive care, anesthesia etc.), an abnormal amount of dead space develops for the patient. Here, 'dead space' refers to the volume in which there is no gas exchange. As a result expired gas in the dead space is returned to the patient at the next inspiration. The ventilator system's dead space mainly consists of the connection between a Y piece and the patient (e.g. a tracheal tube and humidifier/heat exchanger and a measurement tube for measuring gas contents, flow, pressure etc.) Dead space can be relatively large, depending on the design of the ventilator system.

[0003] Since, as a rule, the last gas expired in every breath contains the highest concentration of carbon dioxide, the larger dead space causes greater re-breathing of carbon dioxide.

[0004] US 5 400 778 describes a ventilator system containing a device for reducing the re-breathing of carbon dioxide. In one embodiment, gas is suctioned out of a tracheal tube while gas is delivered at the same time by the ventilator system through an inspiratory line. Additional gas can be supplied through additional connected lines, making it necessary to compensate the regulation of flows for the different volumes supplied to and evacuated from dead space.

[0005] Even if the known device/ventilator system works excellently, there is still a wish to achieve a device producing the same or equivalent effects with a simpler construction, especially with regard to control over evacuated and delivered gas. Achieving a device that can be easily moved between different ventilator system, regardless of the design and application, would also be desirable. Another wish is to achieve a device that ensures simple maintenance of device functionality in the event of a power failure etc.

[0006] One objective of the present invention is to achieve a device that at least in part fulfills one or more of the aforementioned wishes.

[0007] One such device is achieved according to the invention when the device according to the preamble to claim 1 is devised as is evident from the characterizing part of claim 1.

[0008] Advantageous embodiments and refinements of the device according to the invention are evident from the subordinate claims of claim 1.

[0009] A suction means connected to a pump means is achieved when an enclosure is devised with two chambers separated by a moving partition. The interconnected suction means and pump means make it possible to achieve simultaneous evacuation and delivery of a selected volume of gas in a simple and effective fashion. The chambers are connected to dead space via the tubes, and the entire device is compact and easy to transport and move between different kinds of ventilator

systems.

[0010] The first chamber can be devised with an evacuation unit in order to empty the suction means when the movable partition moves back and forth. In the corresponding manner, the second chamber can be devised with a gas connection for delivering fresh gas. Here, the gas connector can be connectable to the ventilator system. This conveys the advantage that no separate gas supply is necessary.

[0011] When equipped with a signal input for receiving signals, the device becomes able to receive signals from the ventilator system. Especially signals indicating where the ventilator is in the breathing cycle. The device is for activation primarily during the end phase of expiration (or during a pause following expiration) in order to reduce dead space in the ventilator system.

[0012] Information on the breathing cycle can alternately be obtained from a flow meter arranged in the ventilator system's expiratory parts.

[0013] Increased accuracy in maintaining a volume of evacuated gas of the same magnitude as the volume of gas delivered is achieved by connecting a first manometer to the first tube or first chamber and a second manometer to the second tube or second chamber. For additional accuracy, pressure in dead space can be determined, either by means of a signal from the ventilator system or by a separate, third manometer connectable to the ventilator system's dead space. When the prevailing pressure (and pressure gradient) is(are) known, the device can be controlled to ensure that the volumes evacuated and delivered are virtually identical.

[0014] The device can also be completely integrated into a ventilator system, thereby achieving a ventilator system according to claim 8.

[0015] Two embodiments of the device will be described below referring to the figures.

FIG. 1 shows a first embodiment of the device connected to a ventilator system, and
FIG. 2 shows a second embodiment of the device connected to a ventilator system.

[0016] FIG. 1 is a general view of a device 2 according to the invention and a ventilator system 4. Here the dividing line designates a possible division between the device 2 and the ventilator system 4. This will be explained in greater detail below.

[0017] The ventilator system 4 can be connected to a patient 6 in order to facilitate, support or control the patient's 6 breathing. In principle, the ventilator system 4 here can consist of any breathing apparatus 8 that can be connected to an air-breathing creature (human or animal). A ventilator, respirator or an anesthetic machine in particular. The breathing apparatus 8 is equipped with a tubing system for connection to the patient 6. In this instance, the tubing system comprises an inspiratory tube 10, a patient connector 12 and an expiratory tube 14.

[0018] The ventilator system's 4 dead space consists almost entirely of the patient connector 12. However, this is not all the volume the patient 6 runs the risk of re-breathing. To this must be added some or all of the patient's 6 dead space. The amount of patient 6 dead space added depends on the type of patient connector 12 used. As a rule, tracheal tubes and tracheotomy tubes cause some of the patient's 6 own dead space to disappear, whereas face masks and nasal connectors do not, as a rule, affect the patient's 6 own dead space. The latter usually have a smaller dead space than the former, so the device according to the invention is most advantageous with patient connectors 12 such as tracheal tubes and tracheotomy tubes.

[0019] Other components can be connected to or be part of the patient connector 12. Humidifiers and heat exchangers (usually referred to as HME's) and measurement channels for flow measurement and/or gas analysis are examples of such components. As a rule, these components increase dead space.

[0020] The device 2 according to the first embodiment comprises an enclosure 16 whose interior is subdivided into a first chamber 18 and a second chamber 20 by a movable partition 22.

[0021] The first chamber 18 is connectable to the patient connector 12 by a first tube 24, and the second chamber 20 is connectable to the patient connector 12 by a second tube 26. More exactly, the chambers 18, 20 are connectable to dead space.

[0022] The partition 22 is connected to a shaft 28 driven and regulated by a control unit 30 so it can be moved in a controlled manner. Any known power transmission unit, i.e. pneumatic, electromagnetic etc., is capable of actuating the shaft 28.

[0023] These components would actually suffice in the simplest version of the device 2. In an initial stage, the partition 22 could be arranged so the volume of the first chamber 18 is zero. The second chamber 20 could simultaneously be filled with fresh gas to a specific positive pressure in relation to an anticipated average pressure in dead space at the time of evacuation/replenishment. (In principle, this would correspond to the patient's 4 positive end expiratory pressure, i.e. PEEP.) In this position, the second chamber 20 would have a virtually maximal volume, e.g. two liters. The partition 22 could be moved a distance, for every evacuation/ filling performed, corresponding to the volume to be evacuated from or added to dead space. With e.g. 20 milliliters as the volume to be withdrawn and replenished respectively, 100 evacuations/fillings could be performed (100 movement steps by the partition 22). It would then be necessary to detach the device 2 in order to return the partition 22 to its starting position (simultaneously emptying evacuated gas and supplying fresh gas.) A different number of evacuations/replenishments would naturally be needed with other volumes.

[0024] The timing of the point at which gas is withdrawn/replenished can be obtained from a signal input

32 for the control unit 30. Information on the breathing cycles is sent from the breathing apparatus 8 to the control unit 30 via a signal line 44.

[0025] However, the simplest version of the above would make it necessary for the device 2 to be devised with a relatively large volume. In addition, it would have to be periodically disconnected from the ventilator system 4. Disconnecting the embodiment of the device 2 shown in the figure. from the ventilator system 4 in order to remove evacuated gas and replenish with fresh gas would not be necessary. The device 2 according to the figure. can therefore operate on a somewhat varied principle in which gas replacement takes place after each evacuation/replenishment.

[0026] The device 2 is accordingly devised with an evacuation unit 34 for the first chamber 18 and a gas connector 36 for the second chamber 20. Evacuated gas can be discharged into atmosphere or connected to the expiratory tube 14 (preferably close to the breathing apparatus 8, shown with a dotted line in the figure) or some special device for collecting gas. The gas connector 36 is connected to the inspiratory tube 10 via a valve 38 and a gas reservoir 40. The gas reservoir 40 is not inherently necessary. In many instances, especially when the ventilator system is devised for adult patients, the inspiratory tube 10 holds a sufficiently large volume of gas to fill the second chamber 20. The risk of expired gas thereby being sucked into the inspiratory tube 10, thereby contributing to re-breathing of carbon dioxide, can be avoided by, e.g. adding a bias flow of gas through the inspiratory tube 10 and expiratory tube 14.

[0027] When evacuation/replenishment are to occur, the partition 22 is moved forward (upward in the figure), causing negative pressure to develop in the first chamber 18 and positive pressure to develop in the second chamber 20. The pressure gradient between the respective chambers 18, 20 and dead space (the patient connector 12) gives rise to a flow of expired gas to the first chamber 18 and a flow of fresh gas to dead space.

[0028] After evacuation/replenishment have been concluded, the partition is returned to its starting position (advantageously in the end position against the first chamber 18, i.e. at the bottom of the figure) Evacuated gas is now forced out into atmosphere (or to a separate vacuum evacuation unit or to the expiratory tube 14, which is suitable when the gas contains an anesthetic or other gases that should not be discharged directly) via the evacuation unit 34. At the same time, the second chamber 20 is filled with fresh gas via the gas connector 36. This can take place at a suitable point in the breathing cycle, e.g. during the introductory phase of an expiration (i.e. after the inspiratory phase following the evacuation/replenishment.)

[0029] The exact times for evacuation and replenishment respectively can vary in the patient connector 12 and even be arranged in the patient 4 below the patient connector 12. Even if the figure schematically depicts evacuation closer to the patient 4 than replenishment,

the reverse circumstance can be employed, i.e. replenishment of fresh gas closer to the patient 4 (or deeper inside the patient 4) than evacuation.

[0030] Even if evacuation/replenishment in each breathing cycle would be advantageous with movement of the partition 22 (e.g. from one end position to the other end position, like a piston stroke), a number of other options is conceivable if the volume to be withdrawn/replenished must be greater than the volume achievable with a partition movement. Thus, this implies that the entire device can be made very compact and operate continuously with a plurality of 'piston strokes' for each breathing cycle. With a volume of 10 ml in every 'piston stroke' and evacuation of 20 ml in each breathing cycle, for example, two 'piston strokes' would be required etc. The advantage of a compact (small and light) device 2 is that it can be placed very close to the patient 4, enabling the use of much shorter tubes 24, 26.

[0031] It is evident that size of the device 2 can vary considerably. The simple version previously described could conceivably hold up to 5 liters of fresh gas or more, whereas the compact version could hold a volume of fresh gas of 10 milliliters or less. Especially in respect to the smaller volumes, other ways of moving the partition are obviously available. For example, the partition could consist of a shuttle, activated by electromagnetic means, able to move between end positions. A roller membrane moved between two positions could work as well as a piston and possibly even display less friction resistance. In other words, all known pumping principles can be applied to this invention.

[0032] The valve 38 is intended for switching the gas outlet on the breathing apparatus 8 to enable the gas reservoir 40 (or second chamber 20) to fill with gas on a periodic basis, preferably during expiration phases. The valve 38 can be devised to divert only part of total flow when diverting gas from the inspiratory tube 10 during the inspiratory phase. Or it can change the entire gas flow for brief periods of time. In some modern breathing machines 8, the latter methods may present certain regulatory problems and the generation of needless alarms. This can be avoided by returning withdrawn gas to the expiratory line 14 from the evacuation unit 34. This would then result in a closed system for the device 2 in relation to the breathing apparatus 8. If the breathing apparatus 8 contains a separate second gas outlet, this outlet could be used.

[0033] The gas reservoir 40, preferably consisting of a bellows or some other variable-volume container, mainly makes it possible for the second chamber 20 to be filled to the same gas pressure (adjustable) in each replenishment. This gas pressure obviously does not need to be identical to the pressure of the gas diverted from the inspiratory line 10. Compression or decompression can take place in the gas reservoir 40 before or in conjunction with the filling of the second chamber 20.

[0034] For complete transferability between different

ventilator systems 4, the valve 38 should be part of the device 2 and devised as an adapter that can be connected onto the inspiratory line 10. Here, it does not matter if the valve 38 is devised with a variable connection diameter or if the device 2 is equipped with multiple valves 38, each of which devised for connection to a specific tube diameter (for the inspiratory line 10.)

[0035] A first valve 42A is arranged for the first tube 24, a second valve 42B is arranged at the evacuation unit 34, a third valve 42C is arranged at the second tube 26 and a fourth valve 42D is arranged at the gas connector 36 to ensure that gases flow in the right direction. The valves 42A, 42B, 42C, 42D can advantageously consist of check valves.

[0036] A first manometer 46 is arranged to measure pressure in the first tube 24, and a second manometer 48 is arranged to measure pressure in the second tube 26 in order to increase accuracy in ensuring agreement of the volumes withdrawn and replenished. In principle, one of the manometers 46, 48 may suffice, but two would convey additional reliability and accuracy. It should be noted that the manometers 46, 48 are by no means essential components. Sufficient accuracy can be achieved without them.

[0037] During periods in breathing cycles in which the device 2 is inactive (is evacuating/replenishing), flow is null in the tubes 24, 26. Placement of the manometers 46, 48 in the tubes 24, 26 (instead of in the chambers 18, 20) makes it possible to even measure pressure in dead space (the patient connector 12). Measured pressure could therefore be used as an indication of the course of the breathing cycle, i.e. be used for determining when evacuation/replenishment should take place.

[0038] A second embodiment of the device 2A is shown in FIG. 2. Components and parts that can be identical have been retained with the same designations as in FIG. 1.

[0039] Please refer to information provided above on these parts. In principle, the differences between the embodiments is as follows.

[0040] The device 2A utilizes a separate gas source 50 for adding fresh gas to the second chamber 20. The separate gas source 50 can consist of a gas cylinder, a compressor, a pump, a wall gas connection or ambient air. This conveys special advantages in cases in which a gas composition other than the one supplied by the breathing apparatus 8 must be initially supplied to the patient 6. This other gas composition can consist of everything from another concentration composition of the gases (e.g. a higher concentration of oxygen) delivered by the breathing apparatus 8 to completely different compositions (medical gases, medication etc.)

[0041] A flow meter 52 is devised for placement in the expiratory line 14, e.g. by means of a tube adapter. The flow meter 52 supplies information on the breathing cycles. The measurement signal is sent to the control unit 30 via a first measurement line 54.

[0042] A third manometer 56 is arranged to measure

the pressure in dead space. The measurement signal is sent to the control unit 30 via a second measurement line 58.

[0043] There are more versions of means for controlling the device 2, 2A than those set forth.

[0044] For example, the evacuation unit 34 can be connected to a vacuum source in order to achieve a constant negative pressure reinforcing the negative pressure generated in the first chamber 18 when the partition 22 moves. This can be used when large amounts of gas must be withdrawn or if the volume of replenished gas is harder to regulate because of the pressure of fresh gas at the gas connector 36.

[0045] Alternately, the evacuation unit 34 can be used to admit gas into the first chamber 18 at the same time as it sucks gas out of dead space. This can be used when small volumes are desired (instead of regulating stroke length, moving the partition 22 etc.) or if replenished gas is harder to regulate because of the pressure of fresh gas at the gas connector 36.

[0046] Conversely, the gas connector 36 can be used in the corresponding fashion.

[0047] In these functional versions, it would be advantageous (sometimes necessary) for one or a plurality of the valves 42A, 42B, 42C, 42D to be adjustable valves and not check valves. Adjustable valves may also be used if certain time delays are desired in evacuation/replenishment. For example, evacuation can be initiated a few milliseconds before replenishment and vice-versa.

[0048] The two described embodiments (including described alternate versions) are fully combinable in respect to components and functions.

[0049] Another advantage of the device 2, 2A that is not explicitly cited above is that the risk of an adverse impact on the lung is reduced (compensation is automatically made for evacuated gas, thereby avoiding hazardous negative pressure).

[0050] Humidification of the fresh gas has not been addressed above. In principle, gas evacuation could cause the extraction of moisture from the patient. Humidifying fresh gas in the known way before replenishment or after fresh gas is pumped into the patient connector 12 can compensate for this. In the device in FIG. 2, the gas supplied separately from a gas source 50 can advantageously consist of humidified gas.

[0051] The tubes 24, 26, and their connection to the patient connector 12 can be devised in a plurality of ways. For example, they can consist of catheters inserted into the patient connector 12 at the transition to the inspiratory line 10 and the expiratory line 14. One of the tubes 24, 26 (the catheter) can then be introduced more deeply (into) the patient 4 than the other. If the first tube 24 is introduced more deeply into the patient, it can also transport mucus and secretion from the patient 4 (and accordingly make separate mucus removal unnecessary.)

[0052] Alternately, the patient connector 12 can be de-

vised with channels for the different functions, and tubes 24, 26 can be connected to these channels.

[0053] A combination of the two (a catheter and a channel) is also possible.

5 [0054] It should be noted that e.g. tracheal tubes with multiple lumina are well-known in the ventilator field.

Claims

10

1. A device (2; 2A) for ventilator systems (4), said device (2; 2A) being intended for reducing dead space (12) in the ventilator system (4) and comprises a first tube (24), connectable to dead space (12) in the ventilator system (4) for supplying a path of flow for the transport of gas from dead space (12) in the ventilator system (4), a suction means (18, 22), connected to the first tube (24), for generating an adjustable negative pressure in the first tube (24), a second tube (26), connectable to dead space (12) in the ventilator system (4), for supplying a path of flow for the transport of gas to dead space (12) in the ventilator system (4), a pumping means (20, 22), connected to the second tube (26), for generating an adjustable positive pressure in the second tube (26) and a control unit (30) devised to regulate the suction means (18, 22) and the pumping means, **characterized in that** the suction means (18, 22) and the pumping means (20, 22) consist of a first chamber (18) and a second chamber (20) respectively in an enclosure (16), separated by a gas-tight, moving partition (22), the control unit (30) being devised to regulate the moving partition (22) to regulate the suction means (18, 22) and the pump means (20, 22).

35

2. A device according to claim 1, **characterized in that** the first chamber (18) is devised with an evacuation unit (34) for evacuated gas, and the second chamber (20) is devised with a gas connector (36) for gas replenishment.

40

3. A device according to claim 2, **characterized in that** the evacuation unit (34) is connectable to the ventilator system (4).

45

4. A device according to claim 2 or 3, **characterized in that** the gas connector (36) is connectable to the ventilator system (4).

50

5. A device according to any of the above claims, **characterized in that** the control unit (30) comprises a signal input (32) for receiving signals from the ventilator system (4), preferably signals related to breathing cycles, the control unit (30) regulating the suction means (18, 22) and the pump means (20, 22) on the basis of the signals received.

55

6. A device according to any of the above claims,
characterized in that a first manometer (46) is con-
nected to the first tube (24) or the first chamber (18).
7. A device according to any of the above claims, 5
characterized in that a second manometer (48) is
connected to the second tube (26) or the second
chamber (20).
8. A device according to any of the above claims, 10
characterized in that a third manometer (56) is de-
vised for connection to the ventilator system (4) for
determining the pressure in the ventilator system's
(4) dead space (12). 15
9. A ventilator system (4) comprising a dead space
(12), **characterized in that** the ventilator system (4)
is devised with a device (2; 2A) according to any of
the above claims. 20

25

30

35

40

45

50

55

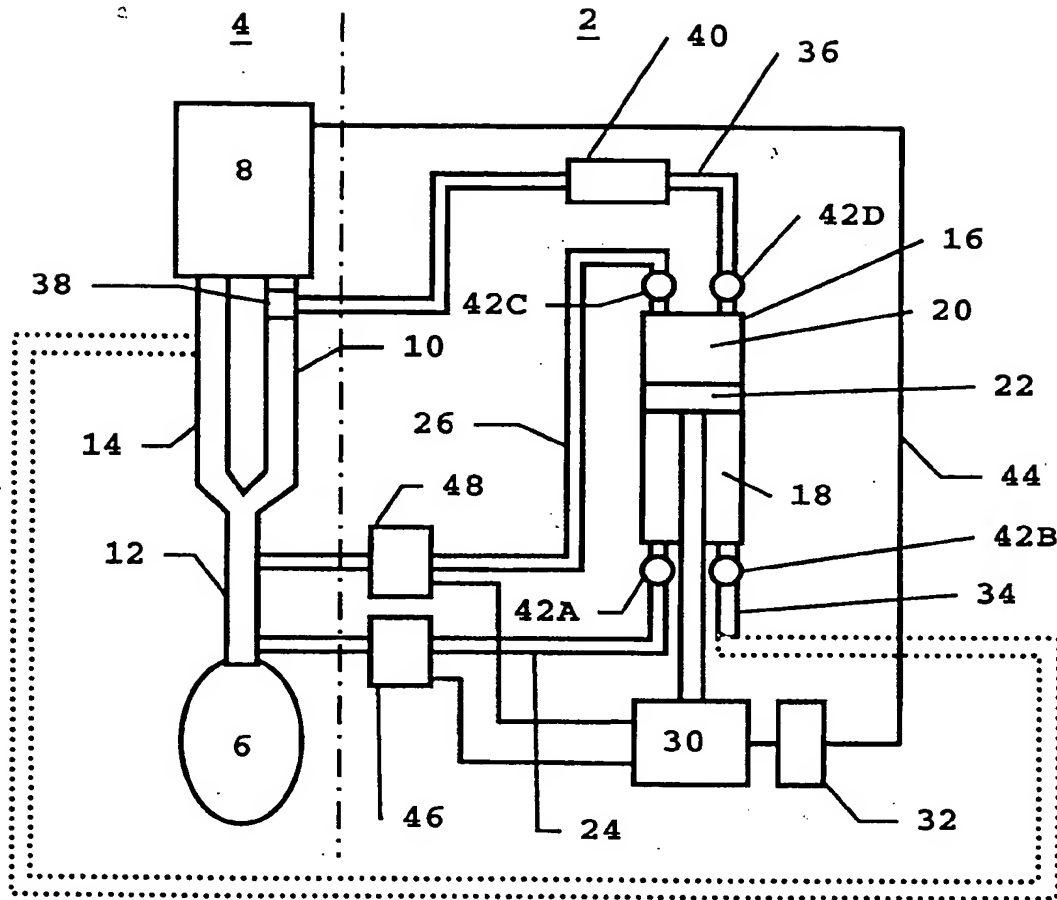


FIG. 1

THIS PAGE BLANK (USPTO)

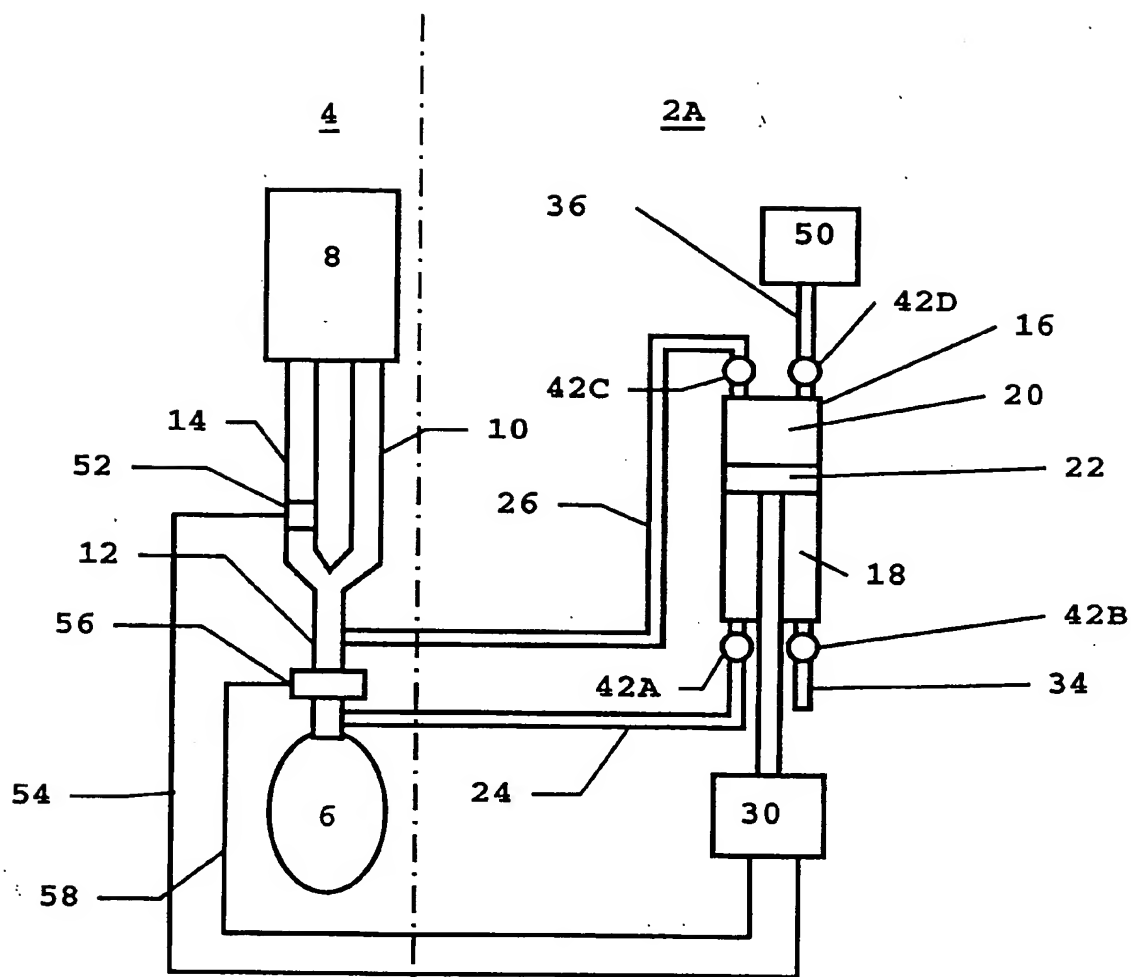


FIG. 2

THIS PAGE BLANK (USPTO)



European Patent
Office

EUROPEAN SEARCH REPORT

Application Number
EP 02 02 5428

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	MUSHIN ET AL: "automatic ventilation of the lungs" 1990, BLACKWELL SCIENTIFIC, OXFORD XP002238747 166160 * page 273 - page 277; figure 12.3 *	1-9	A61M16/00
A	US 4 182 599 A (BROWN ALLEN C ET AL) 8 January 1980 (1980-01-08)		
			TECHNICAL FIELDS SEARCHED (Int.Cl.7)
			A61M
The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 6 May 2003	Examiner Zeinstra, H
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

EPO FORM 1503 (03.82) (P04C01)

**ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.**

EP 02 02 5428

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

06-05-2003

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 4182599	A	08-01-1980	US	3905362 A	16-09-1975
			US	4096858 A	27-06-1978
			BR	7402167 A	07-10-1975
			CA	1007950 A1	05-04-1977
			DE	2446281 A1	30-04-1975
			GB	1489562 A	19-10-1977
			JP	901183 C	15-03-1978
			JP	50078192 A	25-06-1975
			JP	52030793 B	10-08-1977

EPO FORM P0439

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82